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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 14 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Robert Behl
Chief Executive Officer
RadioTherapeutics Corporation
2680 Bayshore Parkway Suite 160
Mountain View, California 94043

Dear Mr. Behl:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed several press releases that pertain to RadioTherapeutics Corporation's RF Ablation System, which includes the RF2000™ Radiofrequency Generator and the family of LeVeen™ Needle Electrodes. The system and its parts are devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act.) As described below, the press releases have misbranded and adulterated the devices within the meanings of sections 502(o) and 501(f)(1)(B), respectively, of the Act.

The radiofrequency generator was granted marketing clearance based on FDA's review of the company's 510(k) premarket notification submission, designated k972441. The intended use for the device is as follows: "The RadioTherapeutics Corp. RF Generator is a medium power electrosurgical generator intended for use with separately approved electrodes for the thermal coagulation of soft tissues." The Modified LeVeen Needle Electrode, cleared pursuant to FDA's review of RadioTherapeutic's 510(k) k962313, is "a disposable monopolar electrosurgical electrode intended to be used in conjunction with FDA approved electrosurgical systems such as those manufactured by RadioTherapeutics, Zomed International, and others for the coagulation necrosis of soft tissues."

In a press release dated April 30, 1998, RadioTherapeutics Corporation announced that it had named Boston Scientific Corporation the exclusive distributor of its RF Ablation System for certain markets in the United States and Japan. The company states that the device utilizes radiofrequency energy to ablate or destroy diseased tissue and that it has been used clinically to treat primary and metastatic liver tumors. The press release states, "In clinical trials, the RadioTherapeutics AF Ablation System is demonstrating its potential to address the significant need for an alternative or complementary treatment for liver tumors that cannot be removed surgically." A similar press release issued by Boston Scientific Corporation quotes Don Woods, President of the Medi-tech division of Boston Scientific as saying, "The agreement with RadioTherapeutics provides Boston Scientific

with the opportunity to help pioneer and bring to market a promising new treatment for patients with liver cancer and other forms of cancer."

A March 30, 1998 press release by the company announced the marketing launch of the product at a joint meeting of the Society for Surgical Oncology and the World Federation of Surgical Oncology Societies. That press release makes numerous references to the use of the device in treating liver cancer and tumors. The press release refers to several presentations addressing the usefulness of the system in treating liver tumors. There is a statement that, "The RadioTherapeutics RF Ablation System addresses the significant need for an alternative or complementary treatment for liver tumors that cannot be removed surgically. Of the more than two million cases of liver cancer and colorectal metastases to the liver that occur worldwide each year, only 10 percent can be treated surgically today." The press release describes a presentation by Dr. Walter Gantert on his use of the system to treat five patients with malignant liver tumors. Your press release quotes the doctor as saying that "these results suggest that radiofrequency ablation with this newly developed multi-array electrode and radiofrequency generator seems to be a safe and effective treatment for small to medium-sized liver tumors, offering a therapeutic option where none existed before." The release also quotes a second physician as concluding that RF ablation, called "a relatively new medical technology for nonresectable tissue," appears promising in comparison to other ablative techniques.

The statements in all of these press releases that the RadioTherapeutics RF Ablation System is effective in treating liver cancers and tumors have changed the intended use of your product. RadioTherapeutics Corporation has not presented to the agency evidence to support these claims. FDA's regulations at 21 CFR 801.4 provide that the intended use of a device refers to the objective intent of the persons responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may be shown by, for example, labeling claims, advertising matter or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

The press releases have misbranded the RF Ablation System within the meaning of section 502(o) because no notice or other information respecting the device was submitted to FDA as required by section 510(k) of the Act and as provided in FDA's regulations at 21 CFR 807.81(a)(3)(ii), which require the submission of premarket notification for a major change or modification in the intended use of a marketed device.

The press releases have adulterated the device within the meaning of section 501(f)(1)(B) because the claims have made the device a class III device under section 513(f) of the Act for which there is in effect neither an approved application for premarket approval pursuant to section 515(a) of the Act nor an approved investigational device exemption as required under section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional and advertising materials used by your firm. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office, within 15 working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the marketplace and steps you plan to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the Director, San Francisco District Office (HFR-PA140), Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

Byron Taft for

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health